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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,795	06/25/2000	BRIAN C. KELLER	270142000300	4731

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EXAMINER	
HENDRICKS, KEITH D	

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/530,795	KELLER ET AL.	
	Examiner	Art Unit	
	Keith Hendricks	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,18-22 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,18-22 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

i) Claims 15, 18-22 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Similar to the rejection previously stated on the record, the newly-recited range of "1.0% to 2%" does not find support in the original specification. The selection of these particular endpoints as part of a claimed range, is not apparent. While it is noted that the examples demonstrate specific phospholipid (lecithin) amounts of 1.0% and 2.0%, there is no support within the specification to provide these two amounts as a range, encompassing any "bilayer-forming lipid" (phospholipid) amount *between* 1.0% and 2.0%. The only liposome-forming lipid range provided in the specification is found at page 5, which states that "the concentration of lipid used to form liposomes in this invention can range from 0.1-50% of the formulation." See also original claim 3. It is again important to note that this is part of the "formulation", which, as previously discussed, differs from the actual "total liposome composition". Regardless, there is no support in the specification for providing the claimed range of "between 1.0% and 2.0%" of bilayer-forming lipids in the lipid composition. Deletion of the rejected new subject matter is required.

ii) Claims 15, 18-22 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is not supported by the original specification for the use of the phrase "consisting essentially of", with regard to the liposome preparation having a "natural bilayer-forming lipid component and an active ingredient component." While it is fully acknowledged that this phrase is well-known and defined in Patent law, it is not relevant to the instant case, where the specification does not find support for the use of this phrase. The liposome component is present merely "between 1.0% and 2.0%" of the liposome preparation, and the specification demonstrates that the "active ingredient component" is a small percentage of the preparation, as well. Thus, it is unclear as to how the preparation may "consist essentially of" only these two components, if they both total less than even 10% of the entire preparation. The examples demonstrate that water, and/or milk, make up the vast majority of the preparation. No other preparations are disclosed, "consisting essentially of" only the two claimed components. Further, the specification does not set forth which additional components would be considered as "not materially affecting the composition", such that one skilled in the art would be apprised of the metes and bounds of the claimed invention.

Further in support of this rejection, it is noted that claims 20-21 recite a liposome preparation "further comprising a stabilizer". These claims depend from claim 15, which does not recite the term "comprising" in relation to the two components of the liposome preparation. Regarding the stabilizer, it is noted that this cannot be dismissed as an insignificant item which does not materially contribute to the claimed composition. It has a specific and necessary function in the preparation. As stated in the specification and claim 21, the amount of stabilizer ranges from 0.05 to 30% of the liposome preparation. Therefore, stabilizer amounts between 3% and 30% would be far above the actual amounts of the "bilayer-forming lipid component". Thus, the claimed invention is not supported by the original specification for the use of the phrase "consisting essentially of", with regard to the liposome preparation having a "natural bilayer forming lipid component and an active ingredient component."

35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 18-22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-21 recite a liposome preparation "further comprising a stabilizer". These claims depend from claim 15, which does not recite the term "comprising" in relation to the two components of the liposome preparation, but rather, recites a preparation "consisting essentially of" the two components. Given this conflicting broad range limitation together with the narrow range limitation, the claims are considered indefinite, since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. In the present instance, claims 20-21 recite the broad recitation, while independent claim 15 recites the narrower statement of the range/limitation. Finally, it is unclear if the stabilizer is to be part of the "bilayer-forming lipid component", i.e. if it is to stabilize the liposome, or if it is simply present in the total "liposome preparation", apart from the two components recited in claim 15, as a stabilizer for another, unspecified function of the entire composition.

Conclusion

NOTE: Due to the conflicting amendment(s) made to the claims, an accurate and effective prior art comparison cannot be made. Applicant has not provided support for "a liposome preparation consisting essentially of a natural bilayer-forming lipid component and an active ingredient component, wherein the lipid component consists of a bilayer-forming lipid concentration of between 1.0% to 2.% of the liposome preparation." The current language of the claims implies that, if the bilayer-forming lipid component is present in an amount of between 1.0% and 2.0%, then the active ingredient component must be present in an amount approaching 98%-99%, if not exactly these amounts. However, there is no support in the specification for such a composition. In fact, there is no range amount provided for the active ingredient component, although the active ingredients used in the examples are present in minor amounts.

Note that applicant's comments at page 5 of the response of March 5, 2004, are inaccurate and misleading, and misrepresent the teachings of the Mehansho reference. Applicant has stated that "as acknowledged by the Office, Mehansho's ratio of divalent mineral salt to edible carrier comprises about 50% to 0.2% divalent mineral salt (or 50% to 99.8% edible carrier). The present claims clearly fall outside of this range." This is inaccurate, at least for the conclusionary rationale provided by applicant that if the referenced preparation comprises about 50% to 0.2% divalent mineral salt, then the remainder must be "50% to 99.8% edible carrier". This is inaccurate and not supported by the reference, for the same reasons that the instant specification does not support a solitary two-component preparation, as

stated immediately above. In both cases, other components are necessarily present, and contribute to the preparation total percentage. However, since applicant's claims have been improperly amended, no accurate prior art comparison may be made, and thus no prior art is applied at this point in prosecution.

Applicant is reminded of the Final status of this application, and thus any proposed amendments after Final rejection which alter the scope of the claims to require a new search and consideration of the prior art, would not be entered in the case at such time. Throughout the prosecution of this application, applicant has frequently amended their claims to alter the scope and content of the claimed invention; however, any such changes will not be considered after Final rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KEITH HENDRICKS
PRIMARY EXAMINER